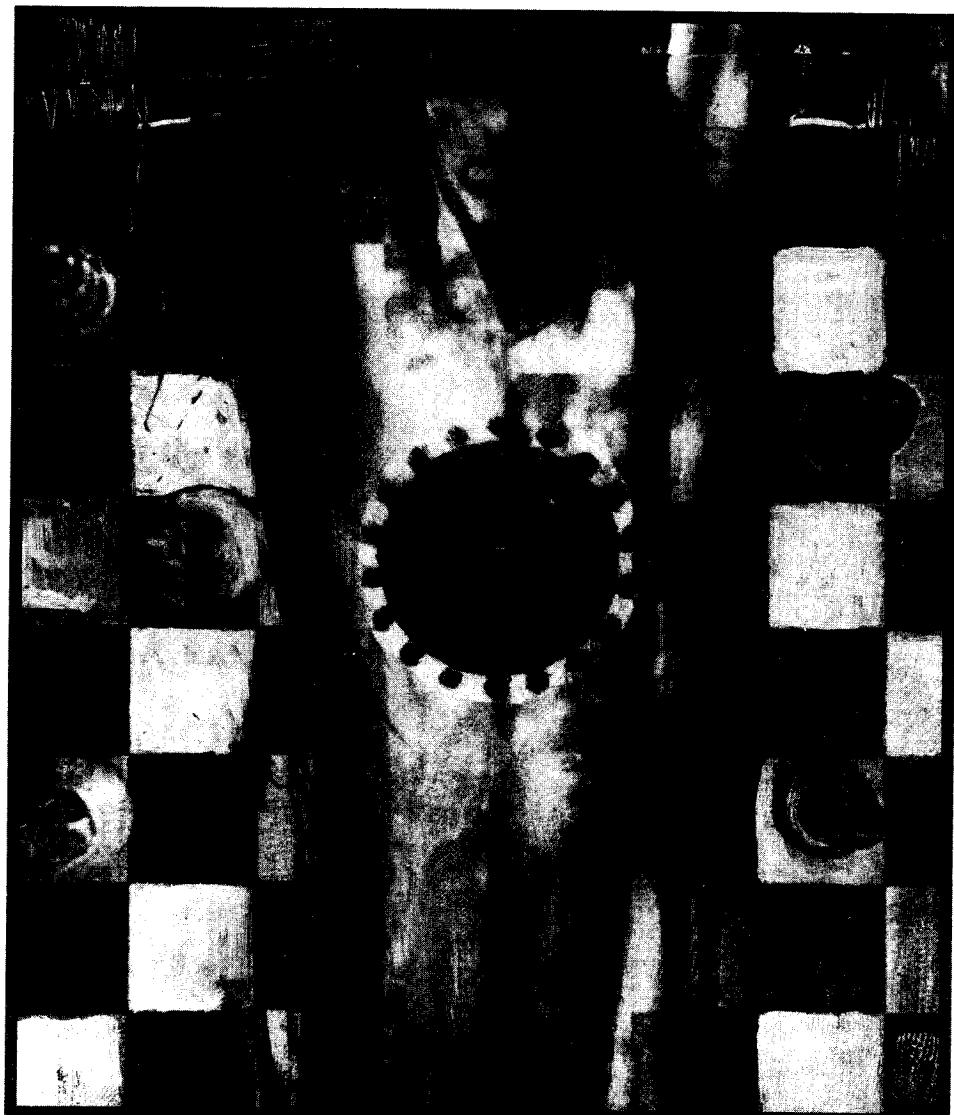


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The symptoms seemed like a run-of-the-mill flu: achy muscles, nausea,

BY MARK SCHOOFS

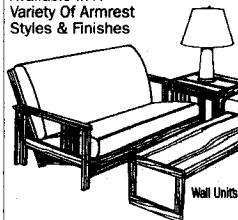


a fever that spiked at 103. But "something just felt different," recalls Peter, who asked that his real name not be used. His lymph nodes were swollen up the side of his neck like a row of "olive

BY

Voice Aug 15, 1995

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pits." And he felt anxious about a "two-minute lapse of judgment" during a sexual encounter couple of weeks earlier. He decided to see his doctor.

Over the next few months, well before flu season hits, hundreds of New Yorkers will feel symptoms similar to Peter's. Most of these people, and their doctors, will shrug off the illness. Only a few will discover, as Peter did, that the culprit is HIV and that their "flu" is what's called conversion sickness: the body's unpleasant signal that it has "converted" to being HIV-positive.

But Peter and 11 others will participate in a small, fascinating trial, scheduled to start this

ponents emerge with slight differences from the previous generation.

What Ho and Shaw discovered, in effect, was that these new generations are produced with lightning speed. And because each one is likely to mutate, it isn't long before the swarm of virus circulating in an individual's body contains countless strains. In the first year, estimates Ho, the virus can produce up to a million variations; in later years, it's up to a billion. So when doctors administer an antiviral drug such as AZT, the virus already has produced variants that drug will not harm. These resistant strains replicate until they are dominant, rendering the drug useless.

Similarly, HIV's prolific mutation may be

**"IT'S A CHESS GAME,"  
SAYS ONE SCIENTIST.  
"WE ARE TRYING TO  
CORNER THE VIRUS,  
BUT WE CAN'T SEE MANY  
MOVES IN ADVANCE."**

month in New York. By catching people as soon as possible after they've been infected, and then administering three powerful drugs that target HIV, researchers believe there's a slight chance that HIV can be eliminated from the body. Their more sober hope is that the virus can be suppressed enough to defer the onset of AIDS, perhaps for years.

"It isn't our intention to hype anything," cautions Dr. David Ho, director of the Aaron Diamond AIDS Research Center, which is conducting the trial. "We are not concocting the potion that would cure AIDS."

But Ho and his colleague, Dr. Martin Markowitz, are clearly excited. A recent revelation about how HIV works in the body, along with new and apparently more potent drugs, suggest that early, aggressive treatment will work. "It's a chess game," says Ho. "We are trying to corner the virus, but we can't see that many moves in advance. If we are lucky enough to win, then great. But if we don't, I think understanding the moves the virus would make is still pretty useful."

**T**hree fundamental reasons prompted Ho and his colleagues to conduct this trial. First was a rarely heralded revelation, discovered independently by Ho and Dr. George Shaw of the University of Alabama at Birmingham, that HIV does not enter a long dormant phase after infection, as was previously believed. Instead, even though an infected person may show no symptoms, HIV is furiously active, replicating at up to 10 billion viral particles per day. (The immune system is also in high gear, trying to keep pace with the virus and gradually losing.)

This discovery has profound ramifications. Scientists have known for some time that HIV is a highly mutable virus. When it infects an immune system cell, HIV hijacks the cell's DNA, turning it into a factory of viral RNA and proteins. In this biological hijacking—carried out by an enzyme called reverse transcriptase—small genetic changes often occur and new viral com-

its greatest advantage against the body's natural defenses. In this month's *Scientific American*, two scientists theorize that the immune system can control several viral strains, but at some point HIV's diversity "befuddles" the body's response.

That leads to the second reason for conducting the trial: For some time after infection—just how long is unclear—the body's population of HIV is homogeneous. Then, says Ho, "the clock begins to tick." The hope is that aggressive treatment at this very early stage can stop the clock—or at least slow it down.

To improve the odds, the researchers are deploying three different drugs. The chance that an individual virus would mutate in all the right places to resist all three of the drugs, says Ho, is roughly one in a trillion. The trial will use AZT as well as two experimental medications: 3TC, which has been shown to work well with AZT, and ABT-538, one of a new class of drugs called protease inhibitors, so named because they target a critical viral enzyme called protease. Early experiments with ABT-538 suggest that it may be considerably more powerful than the other two drugs.

This is the third reason for conducting the trial: Fourteen years into the AIDS epidemic, there finally are medications that just might make a difference. This experiment could shed light on how to deploy them.

What can go wrong? Plenty. First, the drugs could cause serious side effects, especially the newer ones, which simply haven't been monitored for long-term consequences. (The trial will last at least a year.) In combination, the medicines might cause even worse problems than they do individually.

To guard against this, all trial participants will be hospitalized for at least one week, when the drugs are first being administered. "I'm hoping for a river view," quips Peter. Despite such bravado, the specter of side effects scared him enough to designate a health care proxy, and he's told his younger brother about his recent infection "so my boyfriend won't have to tell my family if something goes wrong."

"Nature is much more elegant than what we design," says Ho. "So we could be very, very surprised by the viral strategies." Peter's disease and death could even be accelerated.

**S**till, Peter has a "rational hope" along with a "fantastic hope." Although they don't use those terms, so do the researchers. The fantastic hope amounts to a cure, though everyone, even Peter, avoids that word. Instead, the researchers speak of "knocking out" the virus. "By that," says Ho, "I mean that we couldn't detect any form of active virus in the blood."

Could that happen? "It's possible, if the virus is homogenous enough, and if you prevent every last particle from infecting [immune cells]," says Dr. Robert Gallo, the co-discoverer of HIV. "I think it's theoretically possible. Do I think it will happen? No."

Even if viral particles were cleared from Peter's blood, he would not necessarily be cured. For reasons that remain murky, a small proportion of the immune system cells hijacked by HIV do not immediately produce new virus. Ho likens these cells to embers. If the "big fire" of active virus were put out, the embers of latent virus could still "reignite the whole process."

Eventually, if no virus, latent or active, can be found in Peter's body, he and Ho will have to face the question, "Do we pull the drugs and see what happens?" Gallo knows what he would do. Noting that individual HIV proteins are suspected of causing everything from Kaposi's Sarcoma and other cancers to brain damage, Gallo cautions that the embers of AIDS might never be extinguished: "If I have the right drug, I'm going to treat people forever."

If the virus can't be knocked out, it might be suppressed. This is the "rational hope," and is based on the observation of so-called long-term nonprogressors, people who have lived with the virus and shown no symptoms for 15 years or more. They have a distinctive disease pattern.

Around the time of conversion sickness, the level of active virus particles in the blood spikes at a very high level for everyone. (The person is highly infectious then, more than at any time except near the end of the disease.) Then the "viral load" plunges down to a baseline level. The virus is still replicating furiously, but the body apparently is keeping it in check, forming a delicate but often long-lasting balance. During this time many infected people feel healthy and show few symptoms. In long-term nonprogressors, the baseline viral load tends to be lower than in people who succumb to AIDS more quickly. What Ho hopes to do is shove Peter's baseline down to the level of a nonprogressor, and keep it there.

**T**he hard part of this study is the what-then-question," says Dr. Deborah J. Cotton, a longtime AIDS researcher and clinician at Boston's Massachusetts General Hospital. "If this approach is absolutely stunning," then the obvious response would be to launch "an intensive effort to find people who are seroconverting, conceivably even an attempt to treat high-risk people before they get infected." But she adds, "It's more likely that we are going to see some drop in viral load, but not some kind of sterilization of the bloodstream." In that case, she warns, it isn't so clear that people should jump into this kind of therapy.

Why not? Because a decrease in viral load might not actually prolong life. It seems logical that less virus in the blood would mean less likelihood of disease. But viral load is merely a "surrogate marker," a sign of how HIV is progressing. And it may not be a reliable gauge.

Spencer Cox, a member of the AIDS-treatment watchdog group TAG, cites the infamous example of arrhythmia, in which the heart beats irregularly. Applying common sense, researchers assumed that arrhythmia was a surrogate mark-

er for cardiac failure. Two drugs were developed that suppressed arrhythmia quite effectively, but both drugs also caused fatal heart attacks. "If you just take out the word arrhythmia and put in the words viral burden," says Cox, "we're having the same conversation."

The only sure way to tell whether a drug works, he and Dr. Cotton assert, is to conduct large clinical trials that measure actual survival and disease progression—a painstaking process that takes years. Ho concedes that there are "very few clinical studies" that demonstrate a correlation between viral burden and actual health. But, he argues, "we have to go with our best understanding of the situation."

To Ho, that boils down to "preserving as much [of the immune system] as you can for as long as you can." Besides trusting the reliability of viral load, Ho believes HIV might damage the immune system permanently. He gives a hypothetical example of a patient whose CD4 count (a measure of important immune-system cells) bounces up from 50 to 300 after antiviral treatment. "We have reason to believe the cells that are coming back are not entirely functional," says Ho. "Clearly patients are improved—I don't want to give the wrong message. But it's not the same functional level that you would see in another patient" whose CD4 cells are on the way down.

The disagreement over surrogate markers, currently very hot among AIDS experts, may have a deeper, almost philosophical source: one's faith in our knowledge of AIDS. "We know quite a bit about the pathogenesis of this disease," says Ho, "and everything suggests that all the bad outcomes correlate" with viral load. On the same topic, Cotton says, "Our level of understanding is too primitive to say that."

**E**ven if the trial proves HIV can be conquered if cornered soon enough, the immediate practical benefit will be limited. Catching people at the time of "acute conversion" is very difficult (the reason Ho is having trouble finding suitable candidates for his trial). Many infected people never get conversion sickness. For those who do, the common HIV test might be useless, because it detects antibodies that typically don't show up for six weeks or more. Ho thinks the viral population remains relatively homogenous for three to six months, but Gallo believes the clock might tick much faster. "There's an enormous difference between two hours and two weeks," Gallo says, adding that by "several weeks, the virus is established, I'm sure of it." To make immediate treatment feasible, "you'd need a simple test, like licking a lollipop that changes color if you're infected."

Nothing like that now exists. Peter needed an expensive high-tech test, called a PCR, to find the virus. The PCR can detect HIV about two weeks after infection, but it is not covered by Medicaid or most private insurance. Increasingly, AIDS afflicts the poor, who have little access to basic medical care. And of course, more than 90 per cent of the world's new infections are occurring in the Third World.

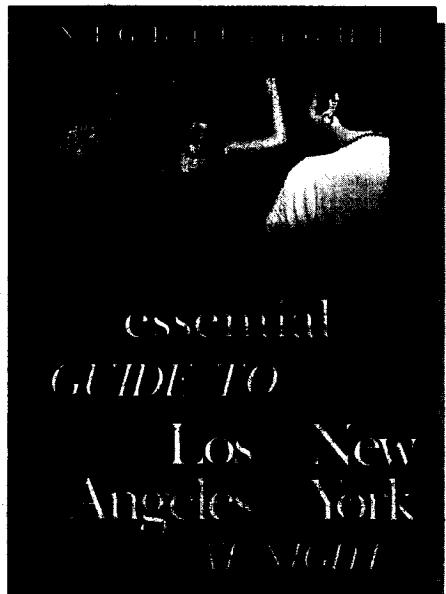
But an effective early therapy might well create a consumer demand big enough for the pharmaceutical industry to develop a cheaper and more sensitive test, perhaps even one that could be used at home. So far, most AIDS counselors recommend testing only tentatively, largely because AIDS is incurable. An effective early therapy would change that attitude.

No doubt many people would still find out that they're infected too late for early treatment. And those already living with HIV would not be helped. Still, this trial might prolong or even save lives, and Peter feels "fortunate" for that chance. ♦

*People who have been infected within the last three months and who want more information about this trial should call Dr. Martin Markowitz at (212) 725-0018.*

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